DETAILED ACTION

Previous Rejections

Applicants' arguments and amended claims filed 12/12/11 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-36, 40 and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Irvin et al. (USP 7,276,184) in view of Westesen et al. (US Patent No. 5,885,486) and further in view of JORDAN et al. (US PG pub. 2002/0103285 A1).

Applicant argues that Irvin produces particles of bioactive agents in crystalline form by pointing to various sections in Irvin's reference and contends that Irvin teaches away from the claimed process of forming amorphous particles starting from crystalline material. According to applicant Westesen teaches in example 19 that product is

recrystallized, therefore the process products formed in prior art is not in an amorphous state but crystalline instead.

Applicant arguments are fully considered but are not persuasive. While it is true that Irvin and Westesen teach crystalline active agents, however, the instant claim 16 also recites suspending solid active agent with dispersant which has crystalline structure. Applicant argues that Westesen teaches in one of the examples that the product is recrystallized, and thus teaches away from the claimed invention which is drawn to avoiding recrystallization. These arguments are not persuasive because while it is true that Westesen teaches recrystallization can be done, the instant claims recite a process that uses poly vinyl alcohol to coat the particles which is responsible for avoiding recrystallization and JORDON as discussed in the rejection above clearly teaches process of coating active agents with polyvinyl alcohol in order to produce good film adhesion and good tensile strength. Since the prior art teaches use of same component for coating pharmaceutically active agent, it would be reasonable to conclude that active agents coated with polyvinyl alcohol will also exhibit similar properties as claimed that will avoid recrystallization. Irvin teaches solid active material in nanoscale and Westesen teaches active agents can be in amorphous form and Jordan provides motivation to add coating to pharmaceuticals to increase film adhesion and strength, thus the claimed invention would have been obvious too one of ordinary skill in the art at the time the invention was made.

Applicant argues that the instant invention discloses particle of an active ingredient, which is normally in crystalline form but which has been transformed into amorphous form, before it could recrystallize and thereby prevent it from recrystallizing. Nothing in Jordan suggests that the tablets e.g. of Jordan's Example 1 were a type that was in amorphous form, but which would recrystallize to a crystalline form and that the coating was applied before recrystallization took place and prevented such recrystallization. Moreover, as discussed above, the Irvin/Westesen combination of references pertain to an active ingredient in crystalline (not amorphous) form. If one were to coat the Irvin/Westesen particles with Jordan's dry film coating, one would end-up with a particle in crystalline form, coated. The differences between Applicants' invention and anything that could be learned from the of Irvin/Westesen/Jordan combination of references are discussed above. The Examiner relies on Rochling for specific additives. None of the additives taught by Rochling could possibly overcome the differences discussed above.

These arguments are not persuasive. Jordan was quoted for teachings of coating actives particles with polyvinyl acetates. Instant specification on page 5, second paragraph which states that “It is extremely surprising that the pulverulent active substance formulations of the invention are substantially more stable than the existing preparations constitutionally closest to them, which are obtainable by melt dispersing, but in which the individual particles **are not encapsulated**”. Therefore in light of above it would be reasonable to conclude that Jordan’s teachings of coating with polyvinyl acetates for use in coating pharmaceutical tablets, nutritional supplements etc.

comprising polyvinyl alcohol which provides an excellent long lasting shining gloss, minimal tackiness, good film adhesion and good tensile strength, (see page 2, [0020] and [0033] and examples) will also provide substantially similar film adhesion with enhanced tensile strength and stability of active ingredient in amorphous form as claimed.

Claim 42 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Irvin et al. (USP 7,276,184) in view of Westesen et al. (US Patent No. 5,885,486) , (JORDAN et al. (US PG pub. 2002/0103285 A1) and further in view of Rochling et al. (USP 6,602,823).

Applicant argues that the Examiner relies on Rochling for specific additives. None of the additives taught by Rochling could possibly overcome the differences discussed above. These arguments are not persuasive. The rationale to combine teachings of Irvin, Westesen and JORDON has been discussed above. Rochling has been cited for teachings of various dispersants used in pharmaceutical art to be mixed with active agents.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612